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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,749	07/11/2001	Avi Ashkenazi	10466/43	5380

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EXAMINER

LAZAR WESLEY, ELIANE M

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/02/2002 13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/903,749

Applicant(s)
ASHKENAZI et al.

Examiner
Christine Saoud

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6, 10 6) ☐ Other:

DETAILED ACTION

Response to Amendment

1. Claims 1-38 have been canceled and claims 39-44 have been added as requested in the amendment of paper #7, filed 11 July 2001. Claims 39-44 are pending in the instant application.

Priority

2. According to the priority statement of 27 August 2002, it appears that the claimed subject matter defined in the instant application is supported by PCT application PCT/US00/04414 filed 2/22/2000. Based on the invention given by Applicant and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is supported by the disclosure PCT/US00/04414, filed 2/22/2000 but is not supported by any of the other applications because the claimed subject matter does not have utility/enablement. The use of the claimed invention for inhibition of VEGF stimulated proliferation of adrenal cortical capillary endothelial cells is first taught in PCT/US00/04414, and this is found to have utility and is enabled by the specification as filed. However, PCT/US98/19437, filed 9/17/1998 does not teach this utility, and therefore, priority is not granted to this application. Accordingly, the subject matter defined in claims 39-58 has an effective filing date of 2/22/2000.

Should the Applicant disagree with the Examiner's factual determination above, it is incumbent upon the Applicant to provide the serial number and specific page number(s) of any parent application filed prior to 2/22/2000 which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which Applicant considers

to have been in possession of and fully enabled for prior to 2/22/2000. Applicant should note that a concise priority claim has not been filed in the form of an amendment to the specification at the time of the instant office action. Applicant may want to file an abbreviated claim of priority as the first sentence of the specification.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 124, line 37. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because of the following informalities: on page 202, line 37, "Pro317" should be "PRO317".

Additionally, Applicants are advised that the ATCC has moved from Rockville, MD to Manassas, VA, effective March 23, 1998. The correct address is now:

American Type Culture Collection
10801 University Boulevard
Manassas, VA 20110-2209

The specification should be amended to reflect the correct address for the ATCC. See page 250, lines 1-2. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 39, 44 and dependent claims 40-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 39 and 44 are indefinite because claim 39 recites "binds" and claim 44 recites "specifically binds". Absent a definition of "specific binding" it is not clear what the difference between the two claims is and what each claim is meant to encompass, given that antibody binding is determined by the variable regions structure and is a "specific" event.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 39-44 are rejected under 35 U.S.C. 102(a) as being anticipated by WO99/58660 (RUBEN et al., 18 November 1999).

WO 99/58660 teaches antibodies to the protein of SEQ ID NO:138, including monoclonal, humanized and labeled antibodies and antibody fragments (see pages 195-197) that would reasonably be expected to bind the polypeptide with the sequence of SEQ ID NO:2 of the

instant application because the proteins share common epitopic regions (see attached sequence comparison).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 39-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over EMBL U48852 (see attached print out for reference) in view of Sibson et al. (WO 94/01548) and Godowski et al. (U.S. Pat. No. 6,030,831). Due to the length of the Sibson reference, only the first 13 pages are provided since these are the only pages which are relied upon for the rejection.

EMBL U48852 provides a written description of a polypeptide which shares approximately 75% amino acid sequence identity to the protein of SEQ ID NO:2. EMBL U48852 does not teach an antibody that binds the polypeptide.

Sibson et al. teach the desirability of expressing nucleic acids encoding proteins or fragments of proteins. It is stated (page 10, line 38) that "Partial or full length cDNAs have great utility once expressed." And (page 11, lines 9-10), "The proteins thus-expressed can be screened for activities of therapeutic or commercial value." It is taught (page 11, line 17) that "Useful antibodies can be raised against the expressed proteins." Monoclonal antibodies are also taught

(page 11, last sentence). Numerous generally applicable uses for antibodies are discussed including *in situ* localization of the encoded protein or fragment (page 11, first paragraph). Methods of antibody production described by Sibson et al. were old and well known in the art (e.g., page 11, lines 20-22).

Godowski et al. teach general methods of producing and using antibodies including monoclonals, fragments, labeled and humanized antibodies (col. 13, lines 47, through col. 14, line 32, col. 15, lines 38-48, and col. 17, lines 18-36) to secreted proteins. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make an antibody, including an labeled, humanized or monoclonal antibody or antibody fragment to the polypeptide of EMBL U48852 because Sibson outlines the uses, advantages and general methods of making antibodies to proteins encoded by expressed nucleic acids and Godowski et al. teach a variety of antibody types and methods of making and using them. One would have been motivated to make such antibodies to use in protein localization or purification, for example.

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices

published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud